

K251835 Yomi Robotic SystemOct 10, 2025
116 days to decisionK251835 · Product code: **PLV** · DentalSource: <https://www.510kdatabase.net/k251835/>**SUBMISSION DETAILS**

| | |
|-----------------------|-------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Dental Stereotaxic Instrument (PLV) |
| Date received | Jun 16, 2025 |
| Decision date | Oct 10, 2025 |
| Days to decision | 116 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Neocis, Inc. |
| Location | Miami, FL, US |
| Contact | Jorge Fernandes |
| 510(k) history | 18 submissions · 18 cleared · 2016-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k251835/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026